THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 105

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

———————

HANS-GEORG LeMAIRE, HEINZ HILLEN, ACHIM MOELLER,
LOTHAR DAUM, THOMAS DOERPER and THOMAS SUBKOWSKI

Junior Party[1]

v.

DAVID WALLACH, HARTMUT ENGELMANN, DAN ADERKA,
DANIELA NOVICK and MENACHEM RUBINSTEIN

Senior Party[2]

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Interference No. 103,625

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HEARD: FEBRUARY 2, 2000

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[1] Application 07/768,443, filed September 26, 1991, now Patent No. 5,344,915, granted September 6, 1994. Accorded benefit of PCT/EP90/00719, filed May 4, 1990. Assigned to BASF Aktiengesellschaft.

[2] Application 07/930,443, filed August 19, 1992. Accorded benefit of U.S. Serial No. 07/524,263, filed May 16, 1990; and Israel Serial Nos. 90339 filed May 18, 1989, 91229 filed August 6, 1989 and 94039 filed April 6, 1990. Assigned to Yeda Research and Development Co. Ltd.

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FINAL DECISION

Before WINTERS, DOWNEY and WILLIAM F. SMITH, Administrative Patent Judges.

DOWNEY, Administrative Patent Judge.

This interference involves a patent to LeMaire et al. (LeMaire), U.S. Patent No. 5,344,915, assigned to BASF Aktiengesellschaft, and an application to Wallach et al. (Wallach), Serial No. 07/930,443, assigned to Yeda Research and Development Co. Ltd.

The subject matter at issue is specific tumor necrosis factor binding proteins having specific N-terminal amino acid sequences and is defined by a single bifurcated count which reads as follows:

Count 1

a) An isolated and purified Tumor Necrosis Factor (TNF) binding protein (TBPII) having the following characteristics:

i. an N-terminal amino acid sequence: Xaa-Pro-Tyr-Ala-Pro-Glu-Pro-Gly-Ser-Thr, where Xaa consists of the following amino acid sequences: Thr, Val-Ala-Phe-Thr-, and Phe- Thr;

ii. the ability to inhibit the cytotoxic effect of TNF-" on murine A9 cells;

iii. a molecular weight of about 30kd in reducing SDS-PAGE analysis.

or

b) A purified and isolated TNF"-binding protein which has a molecular weight of about 42,000 daltons and has at the N terminus the amino acid sequence

Xaa-Thr-Pro-Tyr-Ala-Pro-Glu-Pro-Gly-Ser-Thr-Cys- Arg-Leu-Arg-Glu

where Xaa is hydrogen, a phenylalanine residue (Phe) or the amino acids sequences Ala-Phe, Val-Ala-Phe, Gln-Val- Ala-Phe, Ala-Gln-Val-Ala-Phe, Pro-Ala-Gln-Val-Ala-Phe or Leu-Pro-Ala-Gln-Val-Ala-Phe.

LeMaire claims 1-3 and Wallach claims 33, 34, 36-41, 44-46, 62, and 65-68 correspond to the count.

During the preliminary motion stage of this proceeding, Wallach filed a motion for judgment against LeMaire on the grounds that LeMaire claims 1-3 are unpatentable under 35 U.S.C. § 102 or 35 U.S.C. § 103 over Engelmann et al., "Two Tumor Necrosis Factor-Binding Proteins Purified from Human Urine" J. Bio. Chem. 265: 1531-1536 (Jan. 25, 1990) (Paper No. 21). LeMaire argued that they were entitled to the filing dates of their earlier filed German applications, P 39 15 072 (hereinafter '072) filed May 9, 1989 and P 39 22 089 (hereinafter '089) filed July 5, 1989, which dates precede the publication date of Engelmann et al. and thus the Engelmann et al. reference is not available prior art (Paper No 42).

The APJ granted Wallach motion (item 1a) over the LeMaire opposition stating that

> LeMaire claims 1-2 are directed to a protein having a certain molecular weight and a specific amino acid N terminus and claim 3 is direct to the preparation of the protein of [sic] said [sic] protein [sic]. Each claim identifies the specific amino acid N terminus sequences as a group. Of note <u>each one of the named sequences</u> include at the very least Thr Pro Tyr Ala Pro Glu Pro Gly Set [sic] Thr Cys Arg Leu Arg Glu. Neither

> 072 nor 089 describe a sequence which includes the end portion, Leu Arg Glu, of the
>
> recited sequence. In addition, 072 identifies X_4 [sic, X^4] as probably Thr where claims 1-3 require Pro at this position. (emphasis added)(See Paper No. 80, page 5)

In view of the granting of the Wallach motion (item 1a) for judgment on the grounds of unpatentability of LeMaire claims 1-3, the APJ dismissed the remaining Wallach and LeMaire motions[3] (Wallach motions 1b-1d, 2-5 and LeMaire motions 1-11 identified as items 1b, 1c, [sic: 1d] and 2-16 in the decision on motion) and placed LeMaire under an order to show cause why judgment should not be entered against them.

In response to that order, LeMaire requested final hearing. Both parties filed records. Neither party took testimony.

Wallach is senior party, having been accorded benefit of the filing date of May 18, 1989 of their earlier filed Israel application, No. 90339, filed May 18, 1989.

The issues(s) presented for our consideration[4](See Paper No. 86 by APJ) are as follows:

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[3]The remaining motions were deemed moot in view of the fact that all of LeMaire claims corresponding to the count were found to be unpatentable to LeMaire and LeMaire failed to overcome the threshold question of patentability. Hilborn v. Dann, 546 F.2d 401, 403, 192 USPQ 132, 134 (CCPA 1976), Qadri v. Chu, 18 USPQ2d 1254, 1256 (Bd. Pat. App. & Int. 1990); and M v. V., 6 USPQ2d 1039, 1041 (Bd. Pat. App. & Int. 1987).

[4] The APJ indicated that the parties would be entitled to raise at final hearing: (1) whether the APJ abused her discretion in not deciding Wallach motions 1b, 1c [sic: 1d] and 2-5 and LeMaire motions 1-11 and (2) whether LeMaire has effectively removed the Engelmann et al. reference by demonstrating that the earlier filed German applications satisfy 35 U.S.C. § 112, first paragraph, description requirement. (Paper No. 86)

1. Did the APJ abuse her discretion when she dismissed the remaining Wallach and LeMaire motions and

2. The Wallach motion 1a for judgment. Are LeMaire claims 1-3 unpatentable over Engelmann et al. under 35 U.S.C. §§ 102 and 103 or did LeMaire establish that their earlier filed German applications satisfy 35 U.S.C. § 112, description requirement for the full scope of their claims 1-3 and thus effectively remove the Engelmann reference as prior art.[5]

In addition, Wallach filed a motion to suppress portions of the LeMaire brief (Paper No. 96) The motion stands opposed. (Paper No. 100)

I.

Preliminarily, we note that LeMaire attached to their brief, and cited therein, two references,[6] that were not submitted in compliance with the rules. Evidence which is attached to a brief violates 37 C.F.R. § 1.682 and will not be given consideration at final

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[5] LeMaire clouds this issue by identifying one of the issues before the board as "whether the LeMaire patent and German priority applications, '072 and '089, contain an enabling disclosure under 35 U.S.C. § 112, first paragraph (See LeMaire's brief, page 5, statement 1). On the contrary, as clearly set forth by the APJ in Paper Nos. 80 and 86, the issue is whether the earlier filed applications satisfy the 35 U.S.C. § 112, description requirement. Description and enablement are separate requirements of 35 U.S.C. § 112, Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1564, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991) and Utter v. Hiraga, 845 F.2d 993, 998, 6 USPQ2d 1709, 1714 (Fed. Cir. 1988).

[6] The Merck Manual, Merck Sharp & Dohme Research Laboratories 15th ed. 1987, Chap. 2, pp. 8-9; and "A Urine Inhibitor of Interleukin 1 Activity Affects Both Interleukin 1" and 1$ But Not Tumor Necrosis Factor ". The Journal of Immunology, Vol 139, No. 5 Sept. 1987 pp. 1541-1545.

hearing. Campbell v. Wettstein, 476 F.2d 642, 648, 177 USPQ 376, 380 (CCPA 1973). Accordingly, these publications will not be considered by the Board.

II.

Wallach motion to suppress

Wallach seeks to suppress that portion of the LeMaire brief directed to the question of whether Wallach's belated motion No. 5 should be considered.[7] The motion is granted. As clearly indicated in Paper No. 86, final hearing will be limited to issues, 1 and 2, supra.

III.

Issue 1

Wallach filed a first brief indicating that its sole purpose was to "preserve a right to have the remainder of Wallach's motions considered if LeMaire is successful in establishing that the APJ abused her discretion in failing to consider the LeMaire motions" (See Paper No. 90, filed February 23, 1998, page 8).

APJ indicated that both parties could raise the question of whether the APJ abused her discretion in dismissing the remaining Wallach and LeMaire motions at final hearing (See Paper No. 86).

Wallach mistakenly assume that they have a right to preserve if LeMaire succeeds in establishing an abuse of discretion. To maintain standing with respect to

[7] Wallach belated motion 5 (item 5 in the decision on motion) was dismissed by the APJ. See Paper No. 80

issue 1, Wallach must submit their own arguments with respect to the issue. Wallach did not present any arguments in their brief with respect to the issue of APJ's abuse of discretion, accordingly, the Wallach brief (Paper No. 90) is dismissed.

LeMaire clearly state in their brief that they do not seek review of the APJ's decision not to decide LeMaire motions 2-11(See Paper No. 89, page 6, Argument, paragraph 1). However, from the tone of the LeMaire brief, at pages 11 and 12, one could infer that LeMaire seek review of LeMaire motion 1 (37 C.F.R. § 1.633(f)) because LeMaire argue that their earlier filed applications satisfy 35 U.S.C. § 112, first paragraph with respect to the count. In the LeMaire reply brief (Paper No. 95, page 2), the inference is confirmed where LeMaire allege that the APJ decided LeMaire motion 1 in substance in her decision on motion and they continue to maintain that they are entitled to benefit of the filing dates of their '072 and '089 German applications with respect to the count for the reasons set forth in their brief. However, the decision on motion clearly shows that the LeMaire motion 1 was not decided[8]. Accordingly, the LeMaire arguments regarding the merits of LeMaire motion 1 have been given no consideration.

With respect to the dismissed LeMaire motions, LeMaire do not present any argument in their brief that the APJ abused her discretion in dismissing LeMaire

[8] The standard for determining benefit to antedate a reference with respect to the full scope of the claims, the issue before us, is different from the standard for determining benefit as to a count (emphasis added). See In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614,1617 (Fed Cir. 1989); Anderson v. Norman, 185 USPQ 371 (Comm'r Pats. 1968); Weil v. Fritz, 572 F.2d 856, 196 USPQ 600 (CCPA 1978).

motions 1-11 (items 6-16 in Paper No. 80). Matters not raised in brief are deemed to have been abandoned. Photis v. Lunkenheimer, 225 USPQ 948 (Bd. Pat. Int. 1984).

Accordingly, issue 1 is deemed moot not having been raised in the briefs of either party.

IV.

Issue 2

Patentability of LeMaire claims 1-3

We hold that LeMaire claims 1-3 are unpatentable under 35 U.S.C. §§ 102 or 103 over Engelmann because, on this record, the party LeMaire has not sustained its burden of establishing, by a preponderance of evidence, that their earlier filed German applications satisfy the first paragraph description requirement of 35 U.S.C. § 112, for the full scope of the claims (emphasis added).

By not arguing the merits of the prior art reference relied on in the preliminary motion for judgment, LeMaire conceded that their claims 1-3 are anticipated under 35 U.S.C. § 102 or would have been rendered obvious under 35 U.S.C. § 103 over Engelmann. Fiddes v. Baird, 30 USPQ2d 1481, 1482 (Bd. Pat. App. & Int. 1991). However, LeMaire remain of the position that Engelmann is not available as prior art against them because LeMaire are entitled to the filing dates, May 9, 1989 and July 5, 1989, respectively, of their earlier filed German applications, P39 15 072 and P39 22 089.

It is Wallach's position that LeMaire is not entitled to benefit of those dates with respect to the invention of the claims, because the German applications do not

contain a written description of specific tumor necrosis factor binding proteins which includes the end portion, Leu Arg Glu, of the recited sequence in the LeMaire patent claims. In addition, Wallach point out that the '072 application identifies X_4 as "probably Thr" where claims 1-3 of the LeMaire patent require Pro at this position.

LeMaire claims 1-3

LeMaire claims 1-3 read as follows;

1. (as corrected by Certificate of Correction of November 29, 1994) A purified and isolated TNF"-binding protein which has a molecular weight of about 42,000 daltons and has at the N terminus the amino acid sequence
Xaa Thr Pro Tyr Ala Pro Glu Pro Gly Ser Thr Cys Arg Leu Arg Glu
where Xaa is hydrogen, a phenylalanine residue (Phe) or the amino acid sequences Ala Phe, Val Ala Phe, Gln Val Ala Phe, Ala Gln Val Ala Phe, Pro Ala Gln Val Ala Phe or Leu Pro Ala Gln Val Ala Phe.

2. A protein as claimed in claim 1 in deglycosylated form.

3. A process for the preparation of a protein which has a molecular weight of about 42,000 daltons and has at the N terminus the amino acid sequence
Xaa Thr Pro Tyr Ala Pro Glu Pro Gly Ser Thr Cys Arg Leu Arg Glu
where Xaa is hydrogen, a phenylalanine residue (Phe) or the amino acid sequences Ala Phe, Val Ala Phe, Gln Val Ala Phe, Ala Gln Val Ala Phe, Pro Ala Gln Val Ala Phe or Leu Pro Ala Gln Val Ala Phe, which comprises concentration of the urine of patients with fever and subsequent purification of the retentate obtained in this way by ion exchange and affinity chromatography.

While claim 1 recites "[A] purified and isolated TNF"-binding protein, the claim, in fact, is directed to a genus of eight purified and isolated TNF"-binding proteins having a molecular weight of about 42,000 daltons containing specific N terminus amino acid sequences. The eight purified and isolated TNF"-binding proteins have the following N terminus amino acid sequences:

Seq.1 H Thr Pro Tyr Ala Pro Glu Pro Gly Ser Thr Cys Arg Leu Arg Glu

Seq. 2 Phe Thr Pro Tyr Ala Pro Glu Pro Gly Ser Thr Cys Arg Leu Arg Glu

Seq. 3 Ala Phe Thr Pro Tyr Ala Pro Glu Pro Gly Ser Thr Cys Arg Leu Arg Glu

Seq. 4 Val Ala Phe Thr Pro Tyr Ala Pro Glu Pro Gly Ser Thr Cys Arg Leu Arg Glu

Seq. 5 Gln Val Ala Phe Thr Pro Tyr Ala Pro Glu Pro Gly Ser Thr Cys Arg Leu Arg Glu

Seq. 6 Ala Gln Val Ala Phe Thr Pro Tyr Ala Pro Glu Pro Gly Ser Thr Cys Arg Leu Arg Glu

Seq. 7 Pro Ala Gln Val Ala Phe Thr Pro Tyr Ala Pro Glu Pro Gly Ser Thr Cys Arg Leu Arg Glu

Seq. 8 Leu Pro Ala Gln Val Ala Phe Thr Pro Tyr Ala Pro Glu Pro Gly Ser Thr Cys Arg Leu Arg Glu

Claim 2 requires the protein of claim 1 to be in deglycoslated form.

Claim 3 is directed to the process for preparation of the protein of claim 1 comprising concentrating the urine of patients with a fever and subsequent purification of the retentate obtained in this way by ion exchange and affinity chromatography.

Benefit to antedate a reference

A party may antedate prior art by relying on the benefit of an earlier filed foreign application to establish an effective date earlier than that of the reference. 35 U.S.C. § 119. To be entitled to the benefit of an earlier filed application, the application must disclose the claimed subject matter in compliance with 35 U.S.C. § 112, first paragraph (emphasis added). In re Gosteli, 872 F.2d at 1010, 10 USPQ2d at 1616; In re Scheiber, 587 F.2d 59, 61, 199 USPQ 782, 783-784 (CCPA 1978).

Compliance with the "written description" requirement of §112 is a question of fact and each case must be decided on its own facts. Vas-Cath, 935 F.2d at 1563, 19

USPQ2d at 1116; In re Wertheim, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976). The test for determining compliance with the written description requirement is whether the disclosure of the application, as originally filed, reasonably conveys to the skilled artisan that the inventor had possession of the concept at that time of the later claimed subject matter, rather than the presence or absence of literal support in the specification for the claim language. Vas-Cath, 935 F.2d at 1564, 19 USPQ2d at 1117; In re Kaslow, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983); In re Smythe, 480 F.2d 1376, 1384, 178 USPQ 279, 285 (CCPA 1973) and In re Anderson, 471 F.2d 1237, 1240, 176 USPQ 331, 333 (CCPA 1973). Satisfaction of the written description requirement does not require in *haec verba* antecedence in the originally filed application. In re Lukach, 442 F.2d 967, 970, 169 USPQ 795, 797 (CCPA 1971). How close the original description must come to comply with the description requirement of 35 U.S.C. 112 must be determined on a case-by-case basis. In re Wilder, 736 F.2d 1516, 1520, 222 USPQ 369, 372 (Fed. Cir. 1984).

The German applications

The ‘072 application discloses a protein which has a molecular weight of about 42,000 daltons having at the N terminus the following amino acid sequence X $TX^1YX^2X^3EX^4GSX^5X^6RLR$ which translates to

X $ThrX^1TryX^2X^3GluX^4GlySerX^5X^6ArgLeuArg$

where X is defined as oxygen, phenylalanine (Phe) or the amino acid sequence $X^7X^8PheGlnX^9X^{10}$. When the ‘072 application was filed, X^1-X^{10} were not

determined; but it was stated in the ‘072 application that probably X^1 is Pro or Ala, X^2 is Ala, X^3 is Ala or Pro, X^4 is Thr X^5 is Thr and X^7 is Val or Leu, with X^6 and X^8, X^9 and X^{10} identified only as amino acids.

In addition, the ‘072 application specifically discloses the following three specific N-terminus amino acid sequences (1-3) (Bates 0083)

Sequence 1: $FTX^1YX^2X^3EX^4GSX^5X^6RLR$

Sequence 2: $X^7X^8FQW^9X^{10}FTX^1YX^2X^3EX^4GSX^5X^6RLR$

Sequence 3: $TX^1TX^2X^3EX^4GSX^5X^6RLR$

The TNF"-binding protein in ‘072 was said to be isolated from the urine of patients with fever ($38^{o}C) by first concentrating the patients urine by ultrafiltration or reverse osmosis, and then purifying the retentate by ion exchange chromatography (Example 2, P000079).

The ‘089 application discloses proteins having a molecular weight of about 42,000 daltons and having at the N terminus the amino acid sequences XTPYAPEPGSTCR which translates to XThrProTyrAlaProGluProGlySerThrCysArg where X is hydrogen, a phenylalanine residue (F) or the amino acid sequences AF, VAF, QVAF, AQVAF, PAQVAF or LPAQVAF, and the muteins thereof.

The ‘089 application specifically describes a number of proteins that have the following N-terminus amino acid sequences:

H-ThrProTyrAlaProGluProGlySerThrCysArg (sequence 3a)

PheThrProTyrAlaProGluProGlySerThrCysArg (sequence 1a)

AlaPheThrProTyrAlaProGluProGlySerThrCysArg

ValAlaPheThrProTyrAlaProGluProGlySerThrCysArg

GlnValAlaPheThrProTyrAlaProGluProGlySerThrCysArg

AlaGlnValAlaPheThrProTyrAlaProGluProGlySerThrCysArg (sequence 3b)

ProAlaGlnValAlaPheThrProTyrAlaProGluProGlySerThrCysArg (sequence 2b)

LeuProAlaGlnValAlaPheThrProTyrAlaProGluProGlySerThrCysArg(sequence 2a and 1b)

The TNF"-binding protein in the '089 application was said to be isolated from the urine of patients with fever ($38°C) or from ascites fluid from a patient with ovarian sarcoma (P000107-P000108) and concentrated by ultrafiltration or reverse osmosis, and then the retentate was purified by ion exchange chromatography (P000107, page 2, lines 4-5, page 3, line 5 et seq).

Opinion

LeMaire have the burden to establish by a preponderance of the evidence that their earlier filed applications satisfy 35 U.S.C. § 112, first paragraph. Kubota v. Shibuya, 999 F.2d 517, 27 USPQ2d 1418 (Fed. Cir. 1993). In our view, the German applications('072 and '089) do not reasonably convey to those skilled in the art that LeMaire had possession of the proteins having the N terminus amino acid sequences

or the process of obtaining the proteins of LeMaire claims 1-3. Vas-Cath, 935 F.2d at 1563, 19 USPQ2d at 1116; Forssmann v. Matsuo, 23 USPQ2d 1548, 1551 (Bd. Pat. App.

& Int. 1992). Thus, on this record, we find that LeMaire have failed to effectively remove Engelmann as prior art and we thus hold that LeMaire claims 1-3 are unpatentable under 35 U.S.C. § 102 or §103 over Engelmann.

Turning first to the sequences disclosed in the ‘072 application and comparing them with the sequences in LeMaire claims 1-3 (see Table 1 in the Appendix), we find at least three significant differences between the proteins containing N-terminus amino acid sequences disclosed in the ‘072 application and those now claimed by LeMaire: (1) the ‘072 application discloses only three sequences whereas the involved LeMaire patent claims eight sequences (2) in those three disclosed sequences in the ‘072 application positions: -6, -5, -4, -1, 1(seq. 2 and 3), 3, 5, 6, 8, 11, 12 and 16 are unidentified and could be any amino acid and (3) positions -3 and -2 are identified and do not match.

LeMaire, in their ‘072 application, identify a number of probabilities for various positions. Even with these probabilities, we again find significant differences, to wit, (1) the ‘072 application discloses only three sequences whereas the involved LeMaire patent claims eight sequences; (2) positions -6, -4, -1, 1, 12 and 16 are unidentified and could be any amino acid; (3) positions -5, -3, 2, and 8 are identified

and do not match; and (4) positions 3 and 6 could match with the appropriate selected probability.

Turning to the ‘089 application, we find this application more complete in that it sets forth proteins containing eight specific N-terminus amino acid sequences. Upon comparing the sequences in the ‘089 application with that of LeMaire claim 1 (See Table 2, appendix), it can be readily seen that the ‘089 application does not disclose any amino acid for positions 14, 15 and 16, those positions following the Arg whereas the LeMaire claims recites three additional amino acids, Leu Arg Glu[9]. Hence, positions 14, 15 and 16 could be any amino acid.

While LeMaire acknowledge that the N-terminus amino acid sequences set forth in the LeMaire patent claims are not specifically recited in the 072 application, they argue that this is not fatal. LeMaire state “a subsequent clarification of or change in an original disclosure does not necessarily make that originally [filed] disclosure fatally defective” citing In re Nathan, 328 F.2d 1005, 1008, 140 USPQ 601, 603 (CCPA 1964); In re Magerlein, 346 F.2d 609, 145 USPQ 683 (CCPA 1965); Riester v. Kendall, 159 F.2d 732, 734, 72 USPQ 481, 483 (CCPA 1947).

We disagree with LeMaire. What is fatal is that we find no description in the ‘072 application of a plurality of matching N terminus amino acid sequences as now

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[9] LeMaire, in their opposition paper to the Wallach motion 1a, erroneously indicated that the ‘089 application disclosed a protein able to neutralize the action of TNF-alpha having the following N-terminus amino acid sequence, Xaa-Thr-Pro-Tyr-Ala-Pro-Glu-Pro-Gly-Ser-Thr-Cys-Arg-Leu-Arg-Glu, where Xaa is hydrogen, Phe, Ala-Phe, Val-Ala Phe, Gln, Val Ala Phe, Ala Gln Val Ala Phe, Pro Ala Gln Val Ala Phe, Leu Pro Ala Gln Val Ala Phe.

claimed by LeMaire. Suffice it to say that the ‘072 application disclosure of three proteins having incomplete and misidentified N terminus amino acid sequences is not and cannot be suggestive that LeMaire had possession of the eight proteins with the N terminus amino acid sequences now claimed.

This record establishes that none of the sequences of the ‘072 and ‘089 application match the N terminal amino acid sequences now claimed by LeMaire. However, this does not end the inquiry. Where an earlier filed application does not contain language contained in the claims of a later application, the question is whether the language in the earlier filed application is the legal equivalent of claim language in the sense that the “necessary and only reasonable” construction to be given the disclosure in the earlier filed application by one skilled in the art is the same as the construction which such person would give the language in the claims of the later application. Wagoner v. Barger, 463 F.2d 1377, 1379, 175 USPQ 85, 86 (CCPA 1972).

In order to establish that the earlier filed applications satisfy 35 U.S.C. § 112, description requirement for the now claimed subject matter, LeMaire rely on the doctrine of inherency.

LeMaire argue that the ‘072 and ‘089 application fully support the LeMaire patent claims because the “positive limitation which is the N-terminal amino acid sequence designated in the count [sic: claim] is an inherent characteristic of the purified and isolated TNF" binding protein in ‘072 and ‘089. LeMaire support this argument by reasoning that the proteins as described in the earlier filed German applications are the same as those of

the count [sic: claim] because (1) the proteins of ‘072 and ‘089 have about the same molecular weight, about 42,000 daltons and bind specifically with TNF" ; 2) they are obtained from the “same protein source” i.e., urine from patients with fever ($38^{o}C), and (3) the same methods are used to isolate and purify the protein as the proteins now claimed. LeMaire thus conclude that “the necessary and only reasonable construction to be given LeMaire’s disclosure in the German application ‘072 by one of ordinary skill in the art is one that lends clear support to a protein having an N-terminal acid sequence set forth in the count [sic: claim]”.

We do not find LeMaire’s arguments persuasive. In attempting to establish that the earlier filed applications provide the requisite descriptive support for the LeMaire claims, LeMaire, through their counsel, argue that the disclosed proteins of the earlier filed applications contain these now claimed sequences because they were derived from the same source, urine of patients having a fever ($38^{o}C), and by the same method of isolation and purification. These arguments comprise unsupported attorney argument. It is well settled that attorney argument will not take the place of evidence in the record. Meitzner v. Mindick, 549 F.2d 775, 782, 193 USPQ2d 17, 22 (CCPA), cert. denied, 434 U.S. 854 (1977). LeMaire has submitted no testimony as to what the ‘072 and ‘089 applications would reasonably convey to one of ordinary skill in the art at the time of filing of those applications vis-a-vis the N terminus amino sequences now claimed by the LeMaire involved patent. Behr v. Talbott, 27 USPQ2d 1401 (Bd. Pat. App. & Int. 1992). LeMaire also did not submit any proof that prima facie establishes that the disclosed

subject matter in the ‘072 or ‘089 application, when given its necessary and only reasonable construction, inherently satisfies the limitations of the LeMaire claims.

While LeMaire consistently argue that the source is the same, urine from patients having a high fever, LeMaire do not state that the source is urine from the same patients in each application. In our view, it would appear that LeMaire’s unsupported argument leads to two interpretations. The first interpretation, which would appear at first blush to be more helpful to LeMaire, is that the source of proteins for the ‘072, the 089 and U.S. patent is the same singular pool of patients. A second interpretation, which is not helpful to LeMaire, is that while the protocol for obtention of the protein is the same, the source of the urine is from patients of febrile fever but not from the same singular pool of patients but rather from three differing pools. However, both interpretations fail. As recognized by LeMaire,

N terminal sequence analysis indicates the inhomogeneity of the amino acid sequences found (See the ‘072 application at P000083, the ‘089 application at P000105 and P000110, and the involved patent at column 5, lines 8-10). Therefore, the N terminus sequences of the proteins are unpredictable. In addition, the identified N terminus sequences of the ‘072 and ‘089 applications, see Table 1 and 2, are differing and yet presumably from the same source, urine from patients with a fever ($38^{o}C) Note specifically Seq 2 positions -3 and -2 of ‘072 application. Lastly, the prior art recognizes that more than one TNF" binding protein (TBP-I and TBP-II) is present in the urine of patients with fever. (Wallach exhibits 7-9). While the three sequences of the ‘072

application cannot provide the requisite descriptive support for the now claimed eight sequences, it may be possible that the eight sequences of the '089 application do, but then again it is also possible that they do not. It is well established that inherency may not be established by probabilities or possibilities. In re Oelrich, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981). Hence on this record, we find that LeMaire have not sustained their burden of establishing that the '072 and '089 applications, as originally filed, reasonably convey to the skilled artisan that the inventor had possession of the concept at that time of the later claimed subject matter.

For the foregoing reasons, we hold that LeMaire's claims 1-3 are unpatentable and that LeMaire has failed to effectively remove Engelmann as prior art.

JUDGMENT

It is adjudged that, on the present record, David Wallach, Hartmut Engelmann, Dan Aderka, Daniela Novick and Menachem Rubinstein, the senior party, are entitled to a patent containing claim 67 and Hans-Georg LeMaire, Heinz Hillen, Achim Moeller, Lothar Daum, Thomas Doerper, and Thomas Subkowski, the junior party, are not entitled to their patent containing claims 1-3. Wallach claims 33, 34,36-41, 44-46, 62, and 65, 66 and 68 have been held to be nonallowable by the primary

examiner. Accordingly, we take no position as to these claims, Grove v. Johnson, 22 USPQ2d 1044 (Bd. Pat. App. & Int. 1991).

SHERMAN D. WINTERS Administrative Patent Judge	)))))) BOARD OF PATENT) APPEALS AND) INTERFERENCES)))
MARY F. DOWNEY Administrative Patent Judge	
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MFD/gjh

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